

REMARKS

Status of Claims

Claims 1, 2, 4, 5, 7, 8, 10, 11, 13-15, 21-26, 31, 34, 35, 38-47 and 50 to 54 were pending as shown above and claims 34 and 50-54 were under active examination. Claims 34 and 50-52 have been amended for proper antecedent basis and to specify that the zinc finger protein does not comprise a separate ligand binding domain. Thus, 1, 2, 4, 5, 7, 8, 10, 11, 13-15, 21-26, 31, 34, 35, 38-47 and 50 to 54 are pending as shown above and claims 34 and 50-54 are under active examination.

Rejections Withdrawn

The previous rejection of claims 52 and 54 were newly rejected under 35 U.S.C. §103(a) as allegedly obvious over U.S. Patent No. 7,189,506 ("Lim") in view of Choo was withdrawn. (Office Action, page 18).

35 U.S.C. § 112, 2nd paragraph

Claims 34 and 50-54 were rejected under 35 U.S.C. § 112, 2nd paragraph as alleged indefinite for lacking proper antecedent basis.

Applicants thank the Examiner for the careful attention to the claim language and submit that the foregoing amendments obviate the rejections.

35 U.S.C. § 112, 1st paragraph, written description

Claims 34 and 50-54 were rejected under 35 U.S.C. § 112, 1st paragraph as allegedly not adequately described by the as-filed specification. (Office Action, pages 4-7). It was asserted that (1) the specification does not provide "evidence" that the tested ligands bind Cys2-His2 fingers and (2) the prior art teaches that distamycin, actinomycin D and echinomycin bind to DNA. *Id.*

Applicants traverse the rejection and supporting remarks.

The Examiner asserts that the specification does not provide any evidence that the ligands are binding to the zinc finger protein. *Id.* The foregoing amendment to claim 52 obviates the rejection with regard to claims 52-54.

With respect to claim 30, 50 and 51, it is axiomatic that working examples regarding mechanism of action are never requested to satisfy the written description requirement of 35 U.S.C. § 112 (MPEP, 2163.02, emphasis added):

Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. *See, e.g., Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. *See, e.g., Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997); *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it").

In the case at hand, the specification clearly evinces possession of the claimed subject matter, namely a complex between a zinc finger protein and a ligand, in which the ligand modulates binding of the zinc finger protein to a DNA target site.

Indeed, it is acknowledged that there are working examples regarding increased affinity for a zinc finger protein for its DNA target site in the presence of a ligand. *See*, Office Action, page 5, citing Example 1-2. As well known to the skilled artisan, if the ligand was binding directly to the DNA target site (rather than to the zinc finger protein), this would invariably inhibit binding of the zinc finger protein. Since the reverse is actually exemplified

(namely that the zinc finger protein binds with increased affinity in the presence of the ligand), it is clear that the cited prior art references showing binding of various exemplified ligands to DNA does not change the fact that the as-filed specification clearly evinces possession of complexes between zinc finger proteins and ligands which increase binding affinity of the zinc finger protein. Thus, the assertions regarding the prior art allegedly teaching away from the claimed invention are unfounded and contradicted by the teachings of the as-filed specification. Accordingly, the rejection should be withdrawn.

35 U.S.C. § 103(a)

Claims 34, 50, 52 and 53 were again rejected under 35 U.S.C. §103(a) as allegedly obvious over Christopherson et al. (1992) *Proc. Nat'l. Acad. Sci. USA* 89:6314-6318 ("Christopherson") in view of WO 98/53059 (hereinafter "Choo"). (Office Action, pages 7-12).

Claims 34 and 50-54 were rejected under U.S. Patent No. 6,333,318 (hereinafter "Evans") in view of Choo. (Office Action, pages 12-16).

Both rejections were premised on the assertion that the previous claims encompassed zinc finger proteins "comprising" a separate ligand binding domain, as allegedly taught by Christopherson and Evans. (Office Action, page 13). Thus, as the foregoing amendments to the claims make clear that the ligand binds to the zinc finger protein itself, the rejections cannot be sustained. In particular, Christopherson and Evans all relate only to fusion proteins made up of separate heterologous DNA and ligand-binding domains. Accordingly, there is no combination of either of these references with Choo and teaches or suggests the claimed subject matter and withdrawal of the rejection is in order.

CONCLUSION

For the reasons stated above, Applicants respectfully submit that the pending claims are in condition for allowance.

Respectfully submitted,

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